AWARD NUMBER: W81XWH-16-2-0065

TITLE: Needs, Preferences, and Functional Abilities of Veterans and Service Members with Upper-Limb Amputation

PRINCIPAL INVESTIGATOR: Dr. Linda Resnik, PhD, PT

CONTRACTING ORGANIZATION: Ocean State Research Institute, Inc.
Providence, RI 02908

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S)

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: The purpose of this project is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.

Scope: 1) Describe patterns of prosthesis use and abandonment in the VA and DOD; identify the impact of amputation and prosthesis use on self-reported function, activities and participation; and identify unmet prosthetic needs; 2) conduct a one year follow-up study to examine changes in satisfaction with care and prosthetic services, self-reported function and quality of life; and 3) assess the dexterity and activity performance in upper limb amputees.

Findings/Progress: This initial reporting period (30 September 2016 - 29 September 2017) focused on study start-up activities. There are no findings to report to date. Data collection is ongoing.

15. SUBJECT TERMS

Upper limb amputation; upper limb amputee; quality of care; Evidence-Based Clinical Practice Guidelines; prosthetic device; care satisfaction; amputation rehabilitation; amputation outcomes.

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1. **INTRODUCTION:**

Quality gaps in care of military and Veterans with upper limb amputation have been reported. In 2008, amputees receiving prosthetic care in the VA were reported to be less satisfied than counterparts receiving care in the private sector. In 2011, reported widespread dissatisfaction amongst combat Veterans with upper limb loss led to calls for efforts to evaluate needs of Veterans with traumatic upper limb amputations to improve satisfaction. Major efforts to improve quality of prosthetic care have been made since these studies were conducted. In 2009, the VA reorganized its amputation system of care, and in 2014 the VA and DoD released the Evidence-Based Clinical Practice Guidelines (CPGs) for the rehabilitation of persons with upper limb amputation. It is now time for a comprehensive study to assess the current state of quality and outcomes of amputation rehabilitation for upper limb amputees and to track quality and outcomes over time. Our objective is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.

2. **KEYWORDS:**

Keyword summary: Upper limb amputation; upper limb amputee; quality of care; Evidence-Based Clinical Practice Guidelines; prosthetic device; care satisfaction; amputation rehabilitation; amputation outcomes.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

There are 3 major goals/aims in the approved statement of work (SOW) for this project:

Aim 1: Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs

Aim 2: Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs)

Aim 3: Quantify physical function using a battery of performance based tests.

The table below shows the major tasks associated with each aim/goal, the target completion date, actual completion date (if relevant) and percent complete.

Aim	Activities	Target Completion Date	Completion Date	Percent Complete
Aims 1&2	Regulatory approvals	Month 3	May 2017	100%
	Prepare study staff for survey administration	Month 9	April 2017	100%
	Prepare study data (VA sample)	Month 7	May 2017	100%
	Prepare study data (DoD sample)	Month 7		10%
	Conduct surveys (Aim 1)	Month 19		33%
	Conduct surveys (Aim 2)	Month 31		0%
	Data analysis (Aim 1)	Month 19		0%
	Data analysis (Aims 1 & 2)	Month 33		0%
	Dissemination	Month 36		0%
Aim 3	Regulatory approvals	Month 8	July 2017	100%
	Prepare study staff	Ongoing		80%
	Study coordination	Month 33		35%
	Data collection (Visit 1)	Month 21		13%
	Data collection (Visit 2)	Month 33		0%
	Data Analysis	Month 36		0%
	Dissemination	Month 36		0%

- **What was accomplished under these goals?**

1) Specific objectives and major activities

Specific objectives and major activities accomplished during the Year 1 reporting period (30th September 2016 – 29th September 2017) are described below:

Aims 1 & 2

- Specific Objective 1: Obtain regulatory approvals for data collection sites (fully met)
  - Major Activities:
    - Finalized the Aim 1 and Aim 2 survey instrument (available upon request).
    - Prepared and submitted IRB applications to the VA Central IRB and University of Massachusetts IRB.
    - Submitted documentation of IRB approvals to DoD Human Research Protection Office (HRPO).
    - Prepared and submitted continuing review documentation to the IRB and HRPO.

- Specific Objective 2: Identify Aim 1 and Aim 2 sample (partially met).
  - Major Activities:

        - Established a data sharing agreement between the PVAMC and University of Massachusetts Survey Center (UMASS).
        - Submitted a data request to VINCI (VA database). A data extract was received and used to identify the VA sample for Aims 1 & 2.
        - Cleaned participant contact information.
        - Developed participant tracking systems.

- Specific Objective 3: Begin Aim 1 data collection (fully met).
    - Major Activities:
        - Held a study kick-off meeting at the University of Massachusetts Medical School (UMSS) for all UMSS study staff on April 6th.
        - Held a second training for the UMSS interviewers on June 14th and 15th.
        - Mailed recruitment materials to preliminary participants.
        - Began data collection for Aim 1, approximately 260 total Aim 1 surveys to date.

Aim 3

- Specific Objective 1: Obtain regulatory approvals for data collection sites (fully met)
    - Major Activities:
        - Finalized the Aim 3 protocol and testing forms (available by request).
        - Prepared and submitted IRB applications to the 4 local VA and 1 DoD data collection sites.
        - Submitted IRB approval documentation for the 4 local VA and 1 DoD data collection sites to the DoD HRPO.
        - Prepared and submitted continuing review documentation to the IRB and HRPO.

- Specific Objective 2: Complete all Aim 3 start-up activities (fully met)
    - Major Activities:
        - Developed an Aim 3 policy and procedure guide for local data collection sites.
        - Hired local site coordinators at all 4 VA sites.
        - Held the Aim 3 kick-of meeting for all local site investigators and local coordinators in Tampa, FL from March 27th – 29th.
        - Held a series of trainings for study assessors on functional performance assessments.

- Specific Objective 3: Begin Aim 3 data collection (fully met, ahead of schedule)
    - Major Activities:
        - Developed the testing manual and data collection instrument for Aim 3 local site data collection (instrument available by request).
        - Began Aim 3 (Visit 1) data collection at all local data collection sites.

2) Significant Results or Key Outcomes

There are no results to report to date. Data collection is ongoing.

3) Other Achievements

Infrastructure development

- Executed Year 1 subcontract awards for the 4 VA sites (Seattle, Richmond, Tampa, Gainesville), University of Massachusetts and the Center for the Intrepid.

- Developed a budget tracking and invoicing system for contract administration.

- Developed Standard Operating Procedures for study management.

- Established regular communications to facilitate coordination and insure study fidelity, including:
    - Weekly phone meetings held with the overall study coordinator and staff at each Aim 3 data collection site
    - Monthly Aim 3 local site coordinator meetings
    - Quarterly Aim 3 study assessor meetings
    - Bi-weekly Aim 1 study staff meetings

Regulatory approvals

- Submitted regulatory documents to the University of South Florida (USF). The USF contract does not begin until Year 2. There is no data collection taking place at USF, and no PHI being shared with USF.

Data access and use

- Identifying the DoD study population for Aims 1 and 2 required data use agreements (DUA) with two different DoD agencies. The DUA with the Naval Health Research Center (NHRC) was submitted and is currently under review. The Data Sharing Agreement Application (DSAA) to the Defense Health Agency (DHA) was submitted in July, and we have been working with a DHA team to modify the application so it can be resubmitted. We anticipate that we will have approved agreements by the end of this quarter (December 2017). We will then be able to request data and identify the DoD sample.

Stated goals not met

While we have made significant progress, we have experienced several challenges in meeting stated goals:

1. Regulatory Approval
    a. Goal - By Month 3; Actual - Month 10

Although we did obtain IRB approval at the CFI, we were behind schedule in doing so. There were multiple reasons for the delay. The CFI transitioned to a new IRB system and had a change in leadership while our protocol was under review. We also made some changes to our protocol to address issues identified by a CFI IRB reviewer. This included changing our study protocol so that the PVAMC study team conducts all recruitment for Aims 1 and 2, and the CFI became a data-collection site for Aim 3 only, with no Aim 1 and Aim 2 involvement. In addition, the site- PI at the CFI left his position, so we had to change the PI for this site.

We recently submitted a request for approval for the PI change and change to the scope of work for the CFI to our grants specialist and are waiting on approval. We have received IRB and HRPO approval for these changes.

2. Prepare study staff
    a. Goal - Ongoing

We delayed hiring a site coordinator at the CFI until IRB approval was obtained. Once IRB approval was obtained, the PI there began searching for a site coordinator. The CFI PI has identified a candidate, and is in the processing of hiring this individual for our study.

3. Prepare study data (DoD population)
    a. Goal - By Month 7; Actual - Anticipated December 2017

We have experienced delays in accessing Department of Defense data for this project, although we anticipate receiving approval by the end of the quarter. There are two databases we wish to access to identify the study population – the Military Health System Data Repository (MDR) and Expeditionary Medical Encounter Database (EMED). Our EMED data use agreement with the NHRC is currently under review. The MDR Data Sharing Agreement Application (DSAA), which is required to obtain a DUA, was submitted and reviewed. We are currently working with the DSAA team to modify and resubmit the application. We experienced some issues related to data access and storage requirements. We have been collaborating with a VA team who is creating a joint VA-DoD project called DaVINCI, which is an effort designed to streamline data access for VA and DoD researchers. The DaVINCI team has provided assistance in identifying our data access and transfer processes, Authorization to Operate memos, and other DoD system requirements. Although we are still working on amendments to our requests for DSAA for MDR data, we are hopeful that we will obtain approvals in time to meet our original Aim 1 data collection timeline.

- **What opportunities for training and professional development has the project provided?**

Nothing to report.

- **How were the results disseminated to communities of interest?**

Nothing to report.

- **What do you plan to do during the next reporting period to accomplish the goals?**

During the next reporting period (Year 2), we anticipate accomplishing the following activities to meet the project goals and objectives:

Project Activity	SOW Stated Goal Completion Date
Complete Aim 1 survey data collection for the VA population	Month 19
Identify a DoD sample and complete Aim 1 data collection for this sample	Month 19
Complete Visit 1 data collection for Aim 3	Month 21
Preliminary analysis of Aim 1 survey data	Month 19
Begin Aim 2 data collection	Month 33
Begin Visit 2 data collection for Aim 3	Month 33

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report.

- **What was the impact on other disciplines?**

Nothing to report.

- **What was the impact on technology transfer?**

Nothing to report.

- **What was the impact on society beyond science and technology?**

Nothing to report.

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

During Year 1, we made the following changes to the study approach:

- We had originally planned to collect Aim 1 and Aim 2 survey data using paper and phone-based methods, but modified our plans to use only phone-based data collection. This change was made based on challenges experienced during the pilot phase of this project. We learned that due to the number of skip patterns in the survey, a paper-based survey would have been too challenging for participants to follow. We believe that using only phone-based data collection would result in better data quality. This change was approved by the IRB and submitted to HRPO. The change was deemed non-substantive.

- We made a change to study activities at the Center for the Intrepid data collection site. We originally had intended to utilize the CFI site for Aim 1, Aim 2 and Aim 3

recruitment. However, in the process of completing DUA requests and regulatory paperwork, we learned that we would be able to complete all recruitment for DoD participants through the PVAMC, a change that would enable our team to leverage recruitment efficiencies developed by the PVAMC team. We received IRB and HRPO approval for these changes in August 2017, and recently submitted a request to our grants specialist for final approval for this change in scope of work.

- **Actual or anticipated problems or delays and actions or plans to resolve them**

We experienced some delays in obtaining regulatory approvals, DoD data access, assessor scheduling and staff hiring. These problems and associated actions or plans to resolve any issues are discussed below.

1. IRB Approval at the CFI: This problem was resolved. As discussed in Section 3, we experienced delays in IRB approval at the CFI. We modified the protocol, addressed reviewer concerns, and received IRB approval in July 2017.

2. DoD data access: As previously discussed in Section 3, we experienced delays in accessing DoD data. We are working with the DoD DSAA team to modify our application and resubmit.

3. Problems with assessor scheduling for Aim 3: We experienced some difficulties in scheduling assessors at two of our local sites for Aim 3 participants: Gainesville and Richmond. These two sites do not have local assessors, which reduces scheduling flexibility and makes it more difficult to schedule participant visits. In order to address this issue, we added an assessor to the Tampa/Gainesville team who will be able to see participants at Tampa and also travel to Gainesville. We received prior approval to reallocate funds from Year 1 to support this assessor during Year 2. We also recently identified a local assessor in Richmond, and will be requesting pre-approval to reallocate Year 1 funds to support this assessor during Year 2. Adding these assessors will strengthen our study because it will allow for greater flexibility in scheduling, which will result in better recruitment.

4. Delays in staff hiring: We had delays in staff hiring at the Richmond VAMC and the Center for the Intrepid. We were able to hire a local site coordinator at the Richmond VA in April. We had delayed hiring at the CFI due to delays in IRB approval at the CFI. The site-PI at the CFI has identified an individual to fill local site coordinator role and is in the process of hiring this person.

- **Changes that had a significant impact on expenditures**

The following changes occurred, which impacted our expenditures:

1. Delays in staff hiring: We had delays in staff hiring at the Center for the Intrepid, Richmond VA Medical Center and Providence VA Medical Center. Due to these delays, we have a surplus of Year 1 funding. We developed a spending plan to utilize the carryover funds during Year 2.

2. Recruitment of local participants: We had budgeted for a pool of travel funding for participant travel during Year 1. This travel pool was retained at the Providence site, and the local sites were able to request travel reimbursement as needed. The local

sites focused on recruitment of local participants first, so we did not spend a significant portion of the travel funds. We would like to carry these funds forward to support participant travel during Year 2 because there will be a greater number of non-local participants during this time.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

- **Significant changes in use or care of human subjects**

Nothing to report.

- **Significant changes in use or care of vertebrate animals.**

Nothing to report.

- **Significant changes in use of biohazards and/or select agents**

Nothing to report.

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

  - **Journal publications.**

Nothing to report.

  - **Books or other non-periodical, one-time publications.**

Nothing to report.

- **Other publications, conference papers, and presentations.**

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

  Nothing to report.

- **Inventions, patent applications, and/or licenses**

  Nothing to report.

- **Other Products**

  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Linda Resnik
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	Dr. Resnik has performed work in the area of study protocol development, study instrument selection and development and study oversight for the work of Ms. Ekerholm, Mr. Borgia and Ms. Gill. Dr. Resnik has also conducted trainings for study assessors, provided guidance for quality data collection methods, and conducted quality control review of functional performance assessments.
Funding Support:	*n/a*

Name:	Sarah Ekerholm
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12
Contribution to Project:	Ms. Ekerholm has performed work in the area of study protocol development, study coordination across all study sites, regulatory document preparation and submission, and development of study protocols and procedures. Ms. Ekerholm has also coordinated the submission of data use agreements and maintains the overall study budget.
Funding Support:	*n/a*

Name:	Anisha Gill
Project Role:	Senior Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	10
Contribution to Project:	Ms. Gill has performed work in the area of development of study protocols and procedures, development of study databases and preparation of study data. She has coordinated data cleaning, all mailings for Aim 1, and conducted quality control reviews for Aim 3 data collection. In addition, she has provided technical support to Aim 3 local site coordinators in data collection and entry procedures.
Funding Support:	*n/a*

Name:	Matthew Borgia
Project Role:	Biostatistician/Analyst
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	Mr. Borgia has performed work to identify and randomize the stratified study sample, clean and update contact information, and prepare study data for Aim 1 mailings.
Funding Support:	n/a

Name:	Nora Arriola
Project Role:	Research Assistant/Coordinator (Tampa)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
Contribution to Project:	Ms. Arriola has coordinated data collection activities for the Tampa site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Arriola has coordinated required regulatory submissions for the Tampa site.

Funding Support:	*n/a*

Name:	Matthew Jerrell
Project Role:	Research Assistant/Coordinator (Seattle)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
Contribution to Project:	Mr. Jerrell has coordinated data collection activities for the Seattle site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Mr. Jerrell has coordinated required regulatory submissions for the Seattle site.
Funding Support:	*n/a*

Name:	Ashley Soon
Project Role:	Research Assistant/Coordinator (Gainesville)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
Contribution to Project:	Ms. Soon has coordinated data collection activities for the Gainesville site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Soon has coordinated required regulatory submissions for the Gainesville site.
Funding Support:	*n/a*

Name:	Mandeesha Singh
Project Role:	Research Assistant/Coordinator (Richmond)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Ms. Singh has coordinated data collection activities for the Richmond site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Singh has coordinated

	required regulatory submissions for the Richmond site.
Funding Support:	*n/a*

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

There have been some changes to active support for the PI and senior/key since the original application (in addition to adding our study). These changes are listed below. New active support documents for each referenced personnel are attached in Appendix A. None of these changes have impacted level of effort on this project.

Dr. Linda Resnik: The following changes have been made to Dr. Resnik's support*:*

New

- The project titled "Error Rate Reduction Regarding Lower Limb Prosthesis (LLP)" has been added to active support.
- "Research Career Scientist Award" has been added to active support.
- "Smart Control Modes for Facilitating Use of Multi-DOF Upper-Limb Prosthetics" has moved from pending to active.
- "A Modular Multi-DOF Prosthetic Wrist and Low-Level Autonomous Control for Ease of Use" has moved from pending to active.
- "Variation in Hospital-Based Rehabilitation Services in Joint Replacement and its Impact on Post-Acute Outcomes" has been added to active support.
- "Impact of Hospital-Based Physical Therapy Services on Hospital Readmission: Implications for Bundled Payment" has been added to active support.
- "GAPcare: The Geriatric Acute and Post-acute Care Coordination Program for Fall Prevention in the Emergency Department" has been added to active support.
- "Which Post-acute Care Setting is Best for Patient Outcomes" has been added to active support.

Completed

- "Aligning Resources to Care for Homeless Veterans" is complete.
- A Pilot Study of Two Proxy Measures of Community Integration is complete.
- Learning Related Neural Plasticity Induced by Prosthetic Training: A pilot study is complete.
- Impact of Meditation on Neuropsychiatric Correlates of MTBI and PTSD in Veterans is complete.
- The Measurement of Community Participation using Computer Adaptive Testing (CAT) in Burn Patients is complete.
- Executive Functioning in TBI from Rehabilitation to Social Reintegration: COMPASS is complete.

Dr. Heather Benz: The following changes have been made to Dr. Benz's support:

Completed

- The project titled "Developing clinical trial endpoints for upper limb prostheses" is complete.

Dr. Jill Cancio: The following change has been made to Dr. Cancio's support:

New

- The project titled "Clinical Feasibility of Combining Cranial Electrotherapy Stimulation (CES Alpha-Stim) and Non-invasive Interactive Neurostimulation (InterX) for Optimized Rehabilitation following Extremity Immobilization" has been added to Dr. Cancio's active support.

Dr. Jeffrey Heckman: The following changes have been made to Dr. Heckman's support:

New

- The project titled "3D Printing Foot Orthosis Outcome Testing (3DP FOOT)" has been added to active support.
- The project titled "Criteria for Advanced Prosthetic Foot Prescription" has been added to Dr. Heckman's active support.
- The project titled "Self-management to Improve Function following Amputation (VETPALS)" has been added to Dr. Heckman's active support.

Completed

- The project titled "Studying Treatment and Effectiveness in Prosthetics Systems (STEPS): Utilizing a Regional Collaborative Longitudinal Outcomes Database (CLOUD)", is complete.

Dr. Gail Latlief: The following changes have been made to Dr. Latlief's support:

New

- The project titled "Self-management to improve function following amputation" has been added to Dr. Latlief's active support.

Completed

- The project titled "Home Study of an Advanced Upper Limb Prosthesis" is complete.

Dr. Gayle Reiber: The following changes have been made to Dr. Reiber's support:

Completed

- The project titled "Senior Research Career Scientist Award" is complete.
- The project titled "VA HSR&D Seattle/Denver COIN (Au)" is complete.
- The project titled "Women Veterans in the Women's Health Initiative" is complete.
- The project titled "NIH T-38 Pre and Post-Doctoral Fellowship in Epidemiology is complete.
- The project titled "Center of Excellence for Limb Loss Prevention and Prosthetics Engineering" is complete.
- The project titled "Cognitive Support for Shared Decision Making" is complete.
- The project titled "CVT Home Inhaler Training Study" is complete.
- The project titled "Vet COACH (Veteran peer Coaches Optimizing and Advancing Cardiac Health" is complete.
- The project titled :Assessing Documentation of Dietary Supplements in VA Notes and Structured Fields" is complete.

Dr. Charles Levy: The following changes have been made to Dr. Levy's support:

New

- The project titled "Cognitive Rehabilitation and Brain Activity of Attention-Control in TBI" has been added to active support.
- The project titled "NEA Military Healing Arts Network Telehealth Design, Plan and Service Support" has been added to active support.
- The project titled "The Rural Veterans TeleRehabilitation Initiative Enterprise Wide

Initiative" has been added to active support.

Dr. Joseph Webster: The following changes have been made to Dr. Webster's support:

New

- The project titled "Rehabilitation research and training center on physical disabilities" has been added to active support.
- The project titled "Safety study of percutaneous osseointegrated implants for prosthetic attachment" has been added to active support.

Dr. Jason Highsmith: The following changes have been made to Dr. Highsmith's support:

New

- The project titled "The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance care for Warriors and Veterans following Neuromusculoskeletal Injury of the Lower Limb" has been added to active support.
- The project titled "Prosthetic Smart Socket Technology to Improve Patient Interaction, Usability, Comfort, Fit and Function" has been added to active support.

Completed

- The project titled "Cost Efficacy of Transtibial Interventions" is complete.
- The project titled "Gait Adaptation in Transfemoral Amputees Using Split-Belt Treadmill Training" is complete.

- **What other organizations were involved as partners?**
  - **Organization Name:**
  - **Location of Organization:**
  - **Partner's contribution to the projec**t
    - **Financial support;**
    - **In-kind support**
    - **Facilities**
    - **Collaboration**
    - **Personnel exchanges**
    - **Other.**

Nothing to report

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:**

Nothing to report, not applicable.

- **QUAD CHARTS:** See attached.

9. **APPENDICES:** Appendix A (Other Support Documents) Attached

Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation

PI: Linda Resnik, PT, PhD **Org:** Providence VA Medical Center **Award Amount:** $2,497,349

Study/Product Aims

1. Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs.
2. Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs)
3. Quantify physical function using a battery of performance based tests.

Approach

This 3-part study will provide cross-sectional and longitudinal survey and performance data. Data collection will be done through surveys and functional performance testing. Part 1 will be a cross-sectional survey. Part 2 is a one year longitudinal follow-up survey of respondents from Part 1. Part 3 is an in-person study to collect performance based measures of physical function at two time points, about one year apart.

Timeline and Cost

Activities Project Year (PY)	Year 1	Year 2	Year 3
Identify sampling frame and train interviewers			
Data collection – Part 1			
Data collection – Part 2			
Data collection – Part 3			
Data analysis/dissemination			
Estimated Budget ($K)	**$723,929**	**$920,694**	**$852,816**

Updated: (10-27-2017)

Goals/Milestones

PY1 Goals – Study Launch

- ❑ All IRB Approvals Received
- ❑ Interviewers trained
- ❑ Sampling frame identified
- ❑ Database development complete
- ❑ Part 1 Surveys administered

PY2 Goals – Data collection and early analysis

- ❑ Part 2 surveys administered
- ❑ Gift cards issued Part 2
- ❑ Conduct analyses Aim 1, and preliminary analyses Aim 2

PY3 Goals – Analysis and dissemination

- ❑ Analyze data Parts 2 and 3
- ❑ Submit abstracts and manuscripts

PY1 Budget Expenditure to Date

Projected Expenditure: $723,929
Actual Expenditure: $391,495.69 as of 09/29/2017

Appendix A. Other Support

Key Personnel Previous/Current/Pending Support
Linda Resnik
10-2-17

Previous Support (within the past 5 years)

1) **Title:** Building the Foundation for Clinical Practice of EMG Pattern Recognition for Prosthetic Arm Control (Huang, URI)
Sponsor: NIDRR, Sub to URI
Eileen Campanale, Assistant Director
Sponsored Projects, University of Rhode
Island 70 Lower College Road
Kingston, RI 02881
401-874-4272
Time Commitment: N/A
Period of Performance: 11/1/12-5/31/13
Amount Funded: $17,411
Project Goals: Our objective was to develop new technologies and engineering solutionsthat resolve the difficulties in current EMG PR-based prosthesis control, advancing its adoption in practice.
List of Specific Aims: 1) Conduct and analyze the human subjects study of the proposed new technology development for EMG based pattern recognition control of a multifunction upper limb prostheses.
Overlap: None

2) **Title:** Building the Foundation for Clinical Practice of EMG Pattern Recognition for Prosthetic Arm Control (Huang, NCS)
Sponsor: Subcontract to NCS
NC State University Sponsored Programs
Terri Lomax, Vice Chancellor for Office of Research &
Innovation 2701 Sullivan Drive, Suite 240
Campus Box 7514
Raleigh, NC 27695-7514
919-515-2444
Time Commitment: 11.5 CM (BROWN APPT) **Period of Performance:**
10/2/13-7/31/15
Amount Funded: $75,089
Project Goals: The proposed subcontract will coordinate, conduct and analyze the human subjects study of the proposed new technology development for EMG based pattern recognition control of the multifunction upper limb prostheses.
List of Specific Aims: 1) Conduct and analyze the human subjects study of the proposed new technology development for EMG based pattern recognition control of a multifunction upper limb prostheses.
Overlap: None

3) **Title:** VA DOD Collaboration Guidebook for Healthcare Research
Sponsor: VA HSR&D
David Atkins, MD, MPH

Director, Health Services Research &
Development HSR&D Central Office
810 Vermont Avenue, NW
(10P9H) Washington, DC, 20420

Time Commitment: N/A
Period of Performance: 10/1/12-9/30/13
Amount Funded: $35,000
Project Goals: The purpose of this supplement was to revise the VA/DoD Collaboration Guidebook for Healthcare Research
List of Specific Aims: 1) Revise the VA/DoD Collaboration Guidebook for Healthcare Research.
Overlap: None

4) **Title:** Interface Kinematics of Transhumeral Prosthetic Sockets using XROMM
Sponsor: VA RR&D
Patricia A. Dorn, Ph.D.
Director, Rehab R&D
Service Veterans Affairs
(10P9R)
810 Vermont Avenue,
NW Washington, DC
20420
Time Commitment: N/A
Period of Performance: 4/1/12- 9/30/13
Amount Funded: $68,504
Project Goals: The purpose of this pilot study was to conduct a head to head comparison of two candidate socket designs, the traditional transhumeral (TH) socket design and the "high fidelity" socket design.
List of Specific Aims: Aim 1. To optimize the XROMM system for the measurement of skeletal kinematics while wearing a transhumeral prosthetic socket; Aim 2. To compare comfort, perceived stability, perceived prosthetic weight, and ease of donning and doffing of two upper limb socket designs; Aim 3. To determine bone, joint and sockets kinematics during active range of motion (ROM), vertical loading, and resisted activities.
Overlap: None

5) **Title:** VAMC Neurorehabilitation: Neurons to Networks Center of Excellence (Community Reintegration of Service Members Instrument)(Levin, Houston VA)
Sponsor: VA RR&D
Patricia A. Dorn, Ph.D.
Director, Rehab R&D
Service Veterans Affairs
(10P9R)
810 Vermont Avenue,
NW Washington, DC
20420
Time Commitment: N/A
Period of Performance: 7/1/09-6/30/13
Amount Funded: $73,716
Project Goals: The purpose of this pilot project was to study the relevance of the community reintegration instrument (CRIS) in OEF/OIF veterans with mTBI as defined

through the extensive assessment conducted at the N: N2N Center.
List of Specific Aims: 1) Examine the face validity of the CRIS through focus groups of OEF/OIF veterans with mild TBI and family members with expertise in mild TBI; 2. Field the CRIS in OEF/OIF veterans undergoing evaluation for possible mild TBI and compare CRIS results between those with and without mild TBI and by severity of TBI; Describe mediating and moderating factors of the association between mild TBI and performance
on the CRIS.
Overlap: None

6) **Title:** Studying Upper-Limb Amputee Prosthesis Use to Inform Device Design
Sponsor: USAMRMC BAA
Subcontract to Yale University, USAMRMC BAA 13-1
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St, New Haven, CT 06510-3209
Time Commitment: 1.2 CM (Brown Univ APPT)
Period of Performance: 06/01/14 – 02/28/17
Amount Funded: $99,705
Project Goals/Specific Aims: The proposed project centers on investigating the nature of upper limb prosthesis use in everyday tasks through both an in-home and lab-based study on upper-limb amputees and age- and gender matched normal subjects. By recording performance with an unobtrusive head-mounted camera and examining prosthesis/hand use, we expect to identify shortcomings in current terminal devices and implementations that will inform improvements to existing designs and inspire new classes of devices in the future.
Overlap: None

Current Support

1) **Title:** RFTO # 24 Error Rate Reduction Regarding Lower Limb Prosthesis (LLP), HHSA290201500002
Sponsor: Agency for Healthcare Research and Quality (AHRQ)
Lionel L. Bañez, M.D.
Medical Officer
US Department of Health and Human Services
5600 Fishers Lane 06E69D
Rockville, MD 20857
Time Commitment: .60 CM (Brown Univ Appt)
Period of Performance: 06/20/16 – 08/21/18
Amount Funded: $218,462
Project Goals/Specific Aims: The goal of this systematic review (SR) will be to summarize the analytic validity (reliability), clinical validity (including predictive validity with respect to K-Levels actually attained), and utility (impact on patient-relevant outcomes) of OMTs; it will also describe how these relate to patient- and LLP-specific factors.
Overlap: None

2) **Title:** Needs Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation, W81XWH-16-2-0065
Sponsor: Department of the Army
Elena G. Howell
Grants Officer

US Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-5014

Time Commitment: Consistent with VA APPT
Period of Performance: 10/01/16 - 09/30/19
Amount Funded: $2,499,416
Project Goals/Specific Aims: The objective of this study is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.
Overlap: None

3) Title: Research Career Scientist Award, A9264-S
Sponsor: VA RR&D
Veterans Affairs (10P9R)
Patricia A. Dorn, Ph.D.
Director, Rehab R&D Service
810 Vermont Avenue, NW
Washington, DC 20420

Time Commitment: 12 CM (VA APPT) - This award funds Dr. Resnik's 8/8th VA time and effort as a VA Research Career Scientist.
Period of Performance: 07/01/14 – 06/30/19
Amount Funded: $915,735 Project
Goals/Specific Aims: N/A
Overlap: This award will cover Dr. Resnik's time and effort on the proposed project.

4) Title: Home Study of an Advanced Upper Limb Prosthesis – Renewal, VA A0771-R
Sponsor: VA RR&D
Veterans Affairs (10P9R)
Patricia A. Dorn, Ph.D.
Director, Rehab R&D Service
810 Vermont Avenue, NW
Washington, DC 20420

Time Commitment: Consistent with A9264-S (VA APPT)
Period of Performance: 07/01/16 – 02/28/18
Amount Funded: $549,941
Project Goals: This renewal application includes a new aim to the ongoing VA RR&D Home Study to compare outcomes of subjects using pattern recognition to control the DEKA Arm to those not using this control scheme.
List of Specific Aims:
The purpose of this project is to examine the feasibility, acceptance and benefits of home use of an advanced upper limb prosthetic device as well as the logistical support requirements utilized during 3 months of home usage, and to compare pattern recognition to IMU control of the DEKA Arm..
Overlap: None

5) Title: Smart Control Modes for Facilitating Use of Multi-DOF Upper-Limb Prosthetics
Sponsor: CDMRP
Subcontract to Yale University, USAMRMC BAA 13-1
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St, New Haven, CT 06510-3209

Time Commitment: 1.2 CM (Brown Univ APPT)
Period of Performance: 06/01/15 – 05/31/18
Amount Funded: $115,960
Project Goals/Specific Aims: This proposal will develop "smart" control modes, combined with multisensor volitional control, to enable easy use of a multi-DOFs wrist and one DOF terminal device. The development efforts will be complemented by pre-pilot and pilot human subject studies.
Overlap: None

6) Title: A Modular Multi-DOF Prosthetic Wrist and Low-Level Autonomous Control for Ease-of Use
Sponsor: DOD
Subcontract to Yale University, USAMRMC BAA 13-1
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St, New Haven, CT 06510-3209
Time Commitment: Consistent with A92641 (VA APPT)
Period of Performance: 09/01/15 – 08/31/18
Amount Funded: $96,428
Project Goals/Specific Aims: This project centers on developing and evaluating a novel class of spherical prosthetic wrist that provides a range of motion equal to the unaffected human wrist while adding only two inches to the length of the residual limb.
Overlap: None

7) Title: A Modular Multi-DOF Prosthetic Wrist and Low-Level Autonomous Control for Ease-of Use
Sponsor: DOD
Subcontract to Yale University, USAMRMC BAA 13-1
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St, New Haven, CT 06510-3209
Time Commitment: .72 CM (Brown Univ APPT)
Period of Performance: 09/01/15 – 08/31/18
Amount Funded: $137,236
Project Goals/Specific Aims: This project centers on developing and evaluating a novel class of spherical prosthetic wrist that provides a range of motion equal to the unaffected human wrist while adding only two inches to the length of the residual limb.
Overlap: None

8) Title: Community reintegration, functional outcomes and QOL after upper and lower extremity trauma
Sponsor: BADER
Subcontract to University of Delaware
Laura V. Paller, MPA, CRA
Contract & Grants Specialist, Office of Sponsored Programs
210 Hullihen Hall
Newark, DE | 19716
Time Commitment: Consistent with A9264-S (VA APPT)
Period of Performance: 05/01/15 – 09/29/18
Amount Funded: $192,688
Project Goals/Specific Aims: This grant will bring together a diverse team of stakeholders (individuals who have had catastrophic limb trauma clinicians, policy makers, and research investigators) with many representatives from our participating sites to discuss and agree on a series of common measures and scales

that can help bring standards and uniformity to the field, and will test the toolkit of measures in a population with traumatic upper limb injury.
Overlap: None

9) Title: Multi-Institutional Center on Health Services Training and Research: CoHSTAR
Foundation for Physical Therapy
Sponsor: Foundation for Physical Therapy
Dario Dieguez, PhD
Scientific Programs & Communications Manager
1033 N Fairfax St
Alexandria, VA 22314
Time Commitment: 1.92 CM (Brown Univ APPT)
Period of Performance: 05/01/15 – 04/31/20
Amount Funded: $2,286,921
Project Goals/Specific Aims: The goals of the COE PT HS/PT are to train highly skilled, physical therapist health services/health policy researchers. To mentor young and established researchers in HSR methods and grantsmanship, and to support meritorious preliminary studies that lead to external funding and scholarship.
Overlap: None

10) Title: Variation in Hospital-Based Rehabilitation Services in Joint Replacement and its Impact on Post-Acute Outcomes
Sponsor: CLDR
University of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555-1137
Time Commitment: .02 CM (Brown Univ Appt)
Period of Performance: 07/01/17 – 06/30/18
Amount Funded: $40,000
Project Goals/Specific Aims: The objectives of this proposal are to: 1) estimate and identify source of the hospital-level variation associated with the utilization of hospital-based rehabilitation services after lower extremity joint replacement and 2) examine the association between receipt of hospital-based rehabilitation services and two post-acute outcomes: a. discharge destination and b. hospital readmission
Overlap: None

11) Title: Impact of Hospital-Based Physical Therapy Services on Hospital Readmission: Implications for Bundled Payment
Sponsor: CoHSTAR
Audrey Kydd
121 S. Main Street
Brown University
Providence, RI 02903

Time Commitment: .02 CM (Brown Univ Appt)
Period of Performance: 2/15/17-2/14/18
Amount Funded: $25,000
Project Goals/Specific Aims: The overall objective is to develop a new method of quantifying physical therapy utilization using Medicare data, use that method to explore the variation in hospital-based physical therapy services, and its association with unplanned hospital readmissions
Overlap: None

12) Title: GAPcare: The Geriatric Acute & Post-acute Care Coordination Program for Fall Prevention in the Emergency Department (Goldberg-PI0 Role Mentor)
Sponsor: NIA R03AG056349-01
Time Commitment: .02 CM (VA Appt)
Period of Performance: 7/15/17 -5/31/18
Amount Funded: $120,75
Project Goals/Specific Aims: The overall objective of this investigation is to gather preliminary data on the feasibility of an ED-based multidisciplinary fall prevention intervention. The central hypothesis is that an in-ED intervention involving PT and pharmacy-led assessments and training will lead to fewer falls by giving patients tools for improving function and by decreasing adverse drug events
Overlap: Career Scientist

13) Title: Which Post-Acute Care Setting is Best for Patients' Outcomes?
Sponsor: NIA R01 AG054656-01
Time Commitment: 1 CM (Brown Appt)
Period of Performance: 09/15/17 – 08/30/20
Amount Funded: $381,683
Project Goals/Specific Aims: The overarching goal is to examine PAC utilization and patient outcomes across different conditions and PAC settings to address important gaps in knowledge that hinder the design of current policy efforts undertaken under the Affordable Care Act (ACA) like episode-based bundling of payments and the creation of Accountable Care Organizations, aimed at improving the value of post-acute care
Overlap: None

Pending Support

1) **Title:** Development and User Study of a Highly Adaptive Myoelectric Prosthetic Hand
Sponsor: Subcontract to Yale University, USAMRMC BAA 13-1
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St, New Haven, CT 06510-3209
Time Commitment: .60CM (Brown Univ APPT)
Period of Performance: 09/01/17 – 08/31/21
Amount Funded: $179,737
Project Goals/Specific Aims: The proposed study will focus on the development of a novel class of myoelectric prosthetic hand that balances a very high level of functionality with low mechanical complexity, high durability, light weight, and low cost, and will be highly-adaptive to passively adjust to the shapes of grasped objects.
Overlap: None

2) **Title:** Innovative Approaches to Examine Post-Acute Care Outcomes of Older Adults with Traumatic Brain Injury (Thomas PI)
Sponsor: NIA
Time Commitment: .24 CM (Brown Univ Appt)
Period of Performance: 04/01/18 – 03/31/20
Amount Funded: $448,094
Project Goals/Specific Aims: The overall objective of this proposal is to determine the predictors of outcomes, particularly functional and cognitive improvement and the ability to return home, among older adult patients with TBI.

Overlap: None

3) **Title**: Initial Treatment Approaches and Healthcare Utilization aong Veterans with Low Back Pain (Schmidt PI)

   Sponsor: CoHSTAR

   Time Commitment: .12 CM (Brown Univ. Appt)

   Period of Performance: 2/15/18-2/14/19

   Amount Funded: pending

   Project Goals/Specific Aims: The objective of this research is to gain a better understanding of the initial intervention approaches and important health and utilization outcomes among Veterans with a new diagnosis of LBP.

   Overlap: None

4) **Title**: Rehabilitation following lower limb fractures in persons with multiple sclerosis (Zhang PI)

   Sponsor: NIA

   Time Commitment: 1 CM (Brown Univ. Appt)

   Period of Performance: 7/18/18-6/30/20

   Amount Funded: pending

   Project Goals/Specific Aims: The objective of this application is to better understand rehabilitation access and variation in services rendered for PwMS who experience a lower limb fracture. To accomplish our objective, we will leverage existing secondary data resources that capture national management for a large cohort with MS.

   Overlap: None

Linda Resnik has a Memorandum of Understanding between the Providence VA Medical Center and Brown University that provides for effort up to a 60 hour work week. The VA projects do not count towards Dr. Resnik's Brown University effort. In the event there is an overlap, the effort will be adjusted accordingly.

OTHER SUPPORT

Benz, Heather
Staff Fellow
FDA Center for Devices and Radiological Health

Current

DARPA HAPTIX Interagency Agreement
Award period: 6/2014 – 6/2019
DARPA Biological Technologies Office, $2,000,000
10% effort
Project Goals (specific to role): The scope includes the study of the role of sensory feedback in patient perception of voluntary movement and assessment of the performance of sound-handed individuals and amputees with real and simulated prostheses.
Potential overlap: There is no overlap with this project.

Previous

Title: Comparing qualitative and quantitative approaches to eliciting patient preferences: A case study on innovative upper limb prostheses
Supporting agency: FDA Center for Devices and Radiological Health,
Contracting/Grants Officer: Connie Wilhelm-Miller, connie.wilhelm-miller@fda.hhs.gov
Performance period: 10/2015 – 9/2017
Level of funding: $200,000
Level of effort: 20%
Project goals: Approaches to collecting patient preference information (PPI) are varied, and different methods are applicable to different scenarios. We assessed the views of individuals with amputation about novel prosthesis benefits and risks using different preference elicitation approaches. This work contributed to the science of patient input, identifying the outputs and challenges associated with each approach. Knowledge about the views of individuals with amputation on the benefits and risks associated with innovative prostheses may also inform regulatory decision-making and external scientists and engineers involved in prosthetic development.
Potential overlap: There is no overlap with this project. The survey instruments developed for this project in collaboration with Johns Hopkins University and UC San Francisco provide complementary information about the perspectives of individuals with amputation on benefit/risk trade-offs. The questions are largely methodological questions about survey design for regulatory purposes.

Developing clinical trial endpoints for upper limb prostheses
10/2014 – 9/2015
FDA Critical Path Initiative, $41,000
Contracting/Grants Officer: Connie Wilhelm-Miller, connie.wilhelm-miller@fda.hhs.gov
50% effort
Project Goals: Facilitate the approval of novel devices by identifying and developing validated, reliable, objective criteria that can be used as functional endpoints for upper limb prosthesis clinical trials.
Responsibilities: Scope and protocol development for a systematic review of validated upper limb outcome measures that can be compared to function, quality of life, and health of individuals with intact, normally-functioning limbs. Experimental design for motion capture experiments to quantify functional performance on existing and novel upper limb prosthesis functional outcome measures.
Potential overlap: There is no overlap with this project.

Other Support

Cancio, J

Previous Support

Title:	BADER Toolbox Study: Community Reintegration, Functional Outcomes, and Quality of Life After Extremity Trauma
Time Commitments (Cal. months):	1.2 Months
Supporting Agency:	Henry M. Jackson Foundation
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Aaron Wade USAMRAA 820 Chandler St. Ft. Detrick, MD 21702
Performance Period:	10/1/2013 – 9/30/2017
Level Of Funding (Direct):	$74,749
Brief Description of Project's Goals:	Assist the Military Treatment Facilities (MTF) in providing evidence-based orthopedic rehabilitation care for individuals with extremity trauma.
List of The Specific Aims:	1. Characterize health, physical functioning, community re-integration and emotional functioning in individuals with limb trauma and upper limb amputations who receive outpatient services at MTFs and VAs by using a standardized Toolbox of measures 2. Examine the reliability and concurrent and divergent validity of the Toolbox measures in military samples.

Current Support

Title:	Needs, Preferences, and Functional Abilities of Veterans and Service Members with Upper Limb Amputation
Time Commitments (Cal. months):	1.2 Months
Supporting Agency:	Ocean State Research Institute, Inc.
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Mary T. Ford, MSM, CRA Executive Director Ocean State Research Institute, Inc. 830 Chalkstone Avenue Providence, Rhode Island 02908
Performance Period:	10/1/2016-09/30/2019
Level Of Funding (Direct):	$113,379

Brief Description of Project's Goals:	The proposed study will provide comprehensive cross-sectional and longitudinal data from Veterans and service members with upper limb amputation using a nationally representative sample.
List of The Specific Aims:	1. Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs. 2. Quantify physical function using a battery of performance based tests. 3. Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines
Overlap:	None.
Title:	The Clinical Feasibility of Combining Cranial Electrotherapy Stimulation (CES Alpha-Stim) and Non-invasive Interactive Neurostimulation (InterX) for Optimized Rehabilitation following Extremity Immobilization
Time Commitments (Cal. months):	1.2 Months
Supporting Agency:	Geneva Foundation
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Holly Pavliscak AAMTI Program Manager Telemedicine and Advanced Technology Research Center (TATRC) United States Army Medical Research and Material Command (USAMRMC) Ft. Detrick, MD
Performance Period:	8/1/2017 – 7/30/2018
Level Of Funding (Direct):	$217,311
Brief Description of Project's Goals:	Assessing the feasibility of a dual-device treatment prior to a rehabilitation session for an orthopaedic injury requiring immobilization, and its impact on improving outcomes and decreasing the risk for development of neuropathic pain.

List of The Specific Aims:	1. Evaluate the effectiveness of the Alpha-Stim / Inter-X devices on self-reported pain before and after a rehabilitation session. 2. Evaluate the effectiveness of the Alpha-Stim / Inter-X on range of motion in the area of prolonged immobilization. 3. Evaluate the effectiveness of the Alpha-Stim / Inter-X on reduction of pain medication utilization. 4. Evaluate the effectiveness of the Alpha-Stim / Inter-X on changes in skin temperature, which is a common finding with neuropathic pain.
Overlap:	None.

Pending Support

Title:	iManage TBI: Development and Efficacy Testing of a Symptom Monitoring and Self-Management System for
Time Commitments (Cal. months):	2.4 Months
Supporting Agency:	The University of Delaware
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Vanessa C. Foreman Sr. Business Administrator Center on Assessment Research and Translation University of Delaware STAR Campus 540 S. College Avenue STAR Annex Room 111 Newark, Delaware 19713
Performance Period:	10/30/2017-09/30/2022
Level Of Funding (Direct):	$70,984
Brief Description of Project's Goals:	To develop treatment strategies for improving executive function and memory following TBI.
List of The Specific Aims:	1. Develop treatment strategist using a self-management system, iManage, for self-monitoring the symptoms of TBI. 2. Evaluate iManage and its utility for self-monitoring the symptoms of TBI. 3. Enroll participants to complete the self-monitoring and watch self-management videos independently at their
Overlap:	None.

OTHER SUPPORT

Heckman, JT

Research Funding:

Active:

3D Printing Foot Orthosis Outcome Testing (3DP FOOT)
VA Innovators Network Accelerator Program
VA Puget Sound Health Care System, Seattle, WA.
February ’17
Role: Principal Investigator
Budget: $47,000

Criteria for Advanced Prosthetic Foot Prescription
U.S. Department of Defense
Orthotic and Prosthetics Outcomes Research Program
New York Harbor Healthcare System, New York, NY.
October ’16
Role: Local Site Principal Investigator (PI: Nelson)
Budget: $2,488,273

Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation
U.S. Department of Defense Orthotic and Prosthetics Outcomes Research Program, Providence VA Medical Center, Providence, RI.
Role: Local Site Principal Investigator (PI: Resnick)
October ’16
Budget: $2,497,440

Self-management to Improve Function following Amputation (VETPALS)
U.S. Department of Veterans Affairs Rehabilitation Research and Development
VA Puget Sound Health Care System, Seattle, WA.
Role: Local Site Principal Investigator (PI: Turner)
October ’13
Budget: $1,099,171

Completed:

Studying Treatment and Effectiveness in Prosthetics Systems (STEPS): Utilizing a Regional Collaborative Longitudinal Outcomes Database (CLOUD)
National Institute on Disability and Rehabilitation Research, NIDRR
Role: co-I (PI: Bushnik).
October ’12

Budget: $598,808

Developing an Evidence Based Approach to Address Functional Level Change in Persons Following Transfemoral Amputation
American Orthotic & Prosthetic Association, AOPA
Role: co-I (PI: Bushnik)
November ’12
Annual Budget: $15,000

A Biomechanical and Functional Evaluation of a Microprocessor Controlled Knee Paired with a Powered Ankle-Foot Prosthesis
American Orthotic and Prosthetic Association, AOPA
Role: co-I (PI: Maikos)
November ’12
Annual Budget: $15,000

OVERLAP

There is no potential overlap between any of these projects.

Other Support
Latlief, G

Current

Title: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation
Time Commitment: 1.2 Calendar Months
Supporting Agency: Providence VA Medical Center (prime: US Department of the Army); DoD W81XWH-16-2-0065
Procuring Officer: Mary Reeder, Tampa VA Research and Education Foundation
Performance Period: 10/1/2016-9/30/2019
Level of Funding: $162,254
Project Goals: Provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.
List of Specific Aims: (1) Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs.
(2) Quantify physical function using a battery of performance based tests. (3) Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs).
Overlap: None.

Title: Self-management to improve function following amputation
Time Commitment: 0.60 Calendar Months
Supporting Agency: VA RR&D Merit Review, VA D1143-R
Procuring Officer: Gail Henderson, Jonathan Elder
Performance Period: 7/1/2014-6/30/2018 (no cost extension through 6/30/2019)
Level of Funding: $97,256
Project Goals: To evaluate the effectiveness of a 5-week group-based self-management intervention for Veterans with lower extremity limb loss (VETPALS). VETPALS is an adaption of an empirically supported self-management program, PALS (Promoting Amputee Life Skills). The PALS program demonstrated improved physical and psychosocial functioning when delivered in community-based support groups for amputees, but this program has not been adapted for the needs of Veterans and implemented in the VA healthcare system. This study is a two-arm randomized controlled trial (RCT) to determine the efficacy of VETPALS.
List of Specific Aims: **Aim 1**:Determine the impact of a group-based self-management intervention for Veterans with limb loss (VETPALS) upon physical and psychosocial functioning; **Aim 2:** Determine the impact of a group-based self-management intervention (VETPALS) upon self-efficacy, patient activation, problem solving, quality of life, and positive affect; **Aim 3**: Implementation Evaluation of the VETPALS intervention into the VA health care system by examining 1) actual versus planned participation

(recruitment, retention, treatment engagement, treatment fidelity), 2) barriers and facilitators to implementation, and 3) participant perceptions of the treatment.
Overlap: None

Title: Home Study of an Advanced Upper Limb Prosthesis (DEKA Renewal Study)
Time Commitment: 1.2 Calendar Months
Supporting Agency: VA RR&D Merit (A0771-R)
Procuring Officer: Jonathan Elder
Performance Period: 07/1/2016-6/30/2018
Level of Funding: $282,379
Project Goals: This renewal study includes a new aim to the ongoing VA RR&D Home Study to compare outcomes of subjects using pattern recognition to control the DEKA Arm to those not using this control scheme. The study will assess usefulness and acceptability of the DEKA Arm in a home environment. Data from this study will help inform future VA Prosthetics and Sensory Aids clinical guidelines for prescription of advanced upper limb prosthetic technology.
List of Specific Aims: Aim 1. Identify and describe upper limb amputees who would be appropriate candidates for home use of this advanced prosthesis, as well as those who would not be appropriate; Aim 2. Compare the extent of use of the existing prosthesis to that of the DEKA Arm; Aim 3. Quantify the impact of home use of the DEKA Arm on device satisfaction, performance of functional activities, and the user's quality of life; Aim 4. Quantify the amount and type of technical support and repairs needed during the study, and estimate the number of home study days lost due to service/repair.
Overlap: None.

Title: Community Reintegration, Functional Outcomes and Quality of Life after Upper and Lower Extremity Trauma BADER
Time Commitment: 0.60 Calendar Months
Supporting Agency: Department of Defense
Procuring Officer: Mary Reeder, Tampa VA Research and Education Foundation
Performance Period: 5/1/2015 - 9/30/2017
Level of Funding:
Project Goals: The overarching goal of the BADER Consortium is to assist the Military Treatment Facilities (MTF) in providing evidence-based orthopedic rehabilitation care for individuals with both upper and lower extremity trauma.
Specific Aims: Aim 1: to assess the outcomes in individuals with limb trauma by using a standardized Toolbox of measures to characterize community re-integration, functional outcomes, and quality of life
Aim 2: to examine the reliability and concurrent and divergent validity of the Toolbox measures in military samples
Overlap: None.

Pending

None

Previous

Title: Home Study of an Advanced Upper Limb Prosthesis
Time Commitment: 1.2 Calendar Months
Supporting Agency: VA RR&D (A9226-R)
Procuring Officer: Gail Henderson
Performance Period: 7/1/12-6/30/16
Level of Funding: $881,552
Project Goals: To examine the feasibility, acceptance and benefits of home use of an advanced upper limb prosthetic device as well as the logistical support requirements utilized during 3 months of home usage
Specific Aims: Aim 1. Identify and describe upper limb amputees who would be appropriate candidates for home use of this advanced prosthesis, as well as those who would not be appropriate; Aim 2. Compare the extent of use of the existing prosthesis to that of the DEKA Arm; Aim 3. Quantify the impact of home use of the DEKA Arm on device satisfaction, performance of functional activities, and the user's quality of life; Aim 4. Quantify the amount and type of technical support and repairs needed during the study, and estimate the number of home study days lost due to service/repair.
Overlap: None.

OTHER SUPPORT

Reiber, GE

ACTIVE

VA HSR&D **Salt Lake City COIN** CIN 13-414 (Samore) 2013-2018 3.5 calendar
Health Services Research and Development $3,000,000
This new Center of Innovation advances scientific discovery, incubates novel interventions, promotes research collaboration and engages operational partners through creating an environment within VA where informatics is tightly integrated with health services research and other disciplines. Building on established success in VA informatics research capacity and enhanced understanding of the distributed information space, this research will transform measurement of quality, understanding of socio-technical complexity, surveillance of adverse events, and management of population health. Oversees post-doctoral training program.
Role: Associate Director

PREVIOUS

1. VA RCS 98-353 (Reiber) 1998-2016 1.2 calendar
Senior Research Career Scientist Award $1,244,600
This Research Career Scientist Award was initially funded in 10/98. This is the third, now 7-year award to support Dr. Reiber's extensive research collaboration with investigators in Seattle, Salt Lake City, across the U.S. and abroad in the study of diabetes, lower-limb problems, management of patients with diabetes, and women's reproductive health issues. This award provides time for mentoring post-doctoral fellows and junior faculty.

2. VA HSR&D **Seattle/Denver COIN** (Au) 2013-2018 1.2 calendar
Health Services Research and Development $5,500,000
This Center's mission is to conduct outstanding health services research that promotes Veteran-centered and value-driven care, generate and disseminate knowledge that contributes to the well-being of Veterans, partner with VA policy and operational leaders to implement research findings into clinical care, and train the next generation of health services researchers and leaders.
Role: Core Investigator

3. FOP 14-439 2014 (Reiber) 2014-2015 2.4 calendar
VA Office of Women Veterans Health Care, HSR&D $197,676
Women Veterans in the Women's Health Initiative
This initiative is to facilitate secondary data analysis of extensive Women's Health Initiative (WHI) data on the health of post-menopausal women Veterans and non-Veterans to identify parameters associated with healthy aging among women Veteran participants of WHI and identify parameters associated with premature and excess morbidity and mortality among women Veterans compared to other WHI participants. Findings will be published in a supplement of the Gerontologist in February, 2016.

4. T32 HD052462-06 (Reiber) 2011-2016 0.6 calendar
NIH NICHD $2,289,920
NIH T-38 Pre and Post-Doctoral Fellowship in Epidemiology
This training grant combines with existing graduate degree programs in Epidemiology with multidisciplinary research training experience in epidemiology, biostatistics, health services, environmental health, reproductive, perinatal, and pediatric medicine. The teaching and research activities of 69 faculty provide opportunities for formal training and research experiences. We support 5 pre-doctoral and 2 post-doctoral trainees per year.

5. VA A020940A (Sangeorzan) 2012–2017 0.3 calendar
VA RR&D $4,000,000
Center of Excellence for Limb Loss Prevention and Prosthetics Engineering
The Seattle R&D Center is a nationally recognized Center of Excellence in research and implementation of research relevant to veterans who have had or are facing amputation, and to provide state-of-the-art solutions for the issues of prevention of limb loss and prosthetic prescription. The Center objectives are in three areas: (1) Prevention, (2) Functional Outcomes, (3) Prosthetic Engineering.

6. PPO 13 113-1 (Qing) VA HSR&D IIR 2013-2015 0.6 calendar
Cognitive Support for Shared Decision Making $99,000
Role: Co-Investigator

7. PPO 13-384 (Fan) VA HSR&D 2014-2016 0.6 calendar
CVT Home Inhaler Training Study $99,688

8. VA HSR&D (Nelson) IIR 14-063-3 HSR&D IIR 2015-2019 1.0 calendar
Vet COACH (Veteran peer Coaches Optimizing and $1,093,516
Advancing Cardiac Health) RCT to test the effectiveness of a peer health coach intervention to improve health outcomes for Veterans with multiple CVD risks.
Role: Co-Investigator

9. VA HSR&D (Qing) IIR PPO 2015-2016 0.6 calendar
Assessing Documentation of Dietary Supplements $100,000
in VA Notes and Structured Fields. Uses NLP to identify and link patient use of dietary supplements.
Role: Co-Investigator

OVERLAP
There is no potential overlap between any of these projects.

Other Support

Levy, CE

Active

I21 RX001920-01A1
Sponsor: VA RR&D
Period of Performance: 12/01/15-11/30/17
Title: Cognitive Rehabilitation and Brain Activity of Attention-Control in TBI
Funding: $199,978.
Role: Co-I (William Perlstein, PI):

W81XWH-16-2-0065
Sponsor: Dept. of Defense, U.S. Army Medical Research and Materiel Command DoD
Period of Performance: 9/30/16-9/29/19
Title: Needs Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation
Overall funding: $2,497,440
Role: Site PI (Linda Resnik, PI)

AGR DTD 07-11-2017
Sponsor: Americans for the Arts
Period of Performance: 7.16.17-4.15.18
Title: Creative Forces: NEA Military Healing Arts Network Telehealth Design, Plan and Service Support
Overall funding: $191,899
Role: Co PI

Sponsor: VA Office of Rural Health
Period of Performance: 6/12/17 - 9/30/2021
Title: The Rural Veterans TeleRehabilitation Initiative Enterprise Wide Initiative
Funding: $12,221,965.00
Role: Director and PI

VHA, D-0339 4/01/13 – 3/31/16 2.40 Calendar
VA RR&D $ 824,835
Virtual Environments for Therapeutic Solutions (VETS) mTBI/PTSD Phase II
Project Objectives:
This project will create a prototype virtual human (VH) as a complement to previous work on virtual world environments (VWEs) for mild traumatic brain injury (mTBI) and post-truamatic stress disorder.
Role: Principal Investigator
Program Official: Shirley Groer
Address: 810 Vermont NW (10P9)
Washington, DC 20420

VHA, CIN 13-409 (Mann, PI) 10/1/2013-9/30/2018 3.6 Calendar
VA HSR&D $ 5,000,000
Center of Innovation on Disability and Rehabilitation Research (CINDRR)
Objectives:
The goals of this Center award are to: 1) Develop, evaluate, and implement innovations that maximize activity and participation of Veterans with disabilities and their families; 2) Advance informatics and measurement science in rehabilitation outcomes; 3) Improve independence and health-related quality of life for Veterans with disabilities and their families through technology; 4) Mentor and prepare the next generation of rehabilitation outcomes researchers to assume leadership roles in HSR&D and RR&D; and 5) Foster productive cross-center collaborations and VA Operational partnerships to advance the science and practice of rehabilitation in the VHA.
Role: Co-Investigator and Site Co-Director
Program Official: Mary Jones
Address: 1100 1st Street NE, Suite 6
Washington, DC 20002

VHA, IIR-343 (Uphold, PI) 08/01/2014 – 07/31/2018 1.2 Calendar
VA HSR&D $ 1,099,208
Title: *Utilizing the RESCUE Stroke Caregiver Website to Enhance Discharge Planning*
Objectives:
This study will employ a randomized controlled trial design to test a problem-solving intervention for stroke caregivers that can be delivered during the Veterans' hospital stay, followed by online, in-home sessions.
Role: Co-Investigator
Program Official: John Holden, PhD
Address: 1100 1st Street NE, Suite 6
Washington, DC 20002

VHA, D-1395-P (Uphold, PI) 4/1/2014-3/31/2016 .6 Calendar
VA RR&D $ 198,751
Internet and Telephone Support Intervention for Stroke Caregivers
Objectives:

This project investigates new strategies to teach stroke caregivers how to become integral members of the healthcare team and work together to improve the rehabilitation and recovery of Veterans with strokes.

Role: Co-Investigator
Program Official: Shirley Groer
Address: 810 Vermont NW (10P9)
Washington, DC 20420

VHA, D-1431-P (Romero, PI) 2/1/2014-1/31/2016 .6 Calendar
VA RR&D $ 199,065
Eyes Behind the Video Camera: Partnering with Families for Home Safety
Project Objectives:

This study compares home-safety assessments performed by family members using video cameras to the standard of care, in-person home assessments. We expect that the video camera will give results comparable to in-person assessments, requiring less time and expense form therapists.

Role: Co-Investigator
Program Official: Shirley Groer
Address: 810 Vermont NW (10P9)
Washington, DC 20420

VHA, B-1449-R (Yarrow, PI) 5/2015 to 4/2019 .6 Calendar
VA RR&D $1,100,000
Higher-Than-Replacement Testosterone plus Finasteride Treatment after SCI
Project Objectives:

The study will determine whether this FDA-approved pharmacologic therapy restores musculoskeletal integrity, neuromuscular function, body composition, and metabolic health in hypogonadal men with chronic motor incomplete spinal cord injury (SCI). An important concept of this proposal is that finasteride co-administration reduces prostate cancer risk and completely inhibits the known adverse effects of testosterone on prostate enlargement

Role: Co-Investigator
Program Official: Audrey Kusiak, PhD
Address: 1100 First Street, NW (10P9R)
Washington, DC 20002

JW140063 (Winter, PI) 4/2015 to 3/2019 .6 Calendar
Department of Defense (DOD) $ 1,781,608
Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans
Project Objectives:

This project looks at a driving intervention compared with at standard treatment for combat Veterans.

Role: Co-investigator
Program Official: Doug Medcalf
Address: 820 Chandler St.
Fort Detrick, MD 21702

N08-FY12Q1-S5-P00058 10/1/2012-9/30/2016 1.2 Calendar
VA Office of Rural Health $ 559,000
Rural Veterans Telerehabilitation Initiative Expansion, Proliferation and Dissemination Project
Project Objectives:

The goal of this demonstration project is to develop and implement a program of rehabilitation for rural veterans using secure in-home internet video to connect Veterans to therapists, physicians,

and other health care providers stationed at the medical center. In addition, we will mentor the White River Junction and Richmond facilities to develop their own similar projects.

Role: Project Director
Program Official: Michelle Winslow
Address: 140 Fountain Parkway, Suite 600
St. Petersburg, FL 33716

PREVIOUS

W81XWH-11-1-0454 (Winter, PI) 9/1/2011-3/2/2015 .6 Calendar
Dept. of Defense, U.S. Army Medical Research and Materiel Command, Telemedicine and Advanced Technology Research Center $155,000
Efficacy of a Driving Intervention Program on Safe Community Mobility for Returning Combat Veterans
Project Objectives:

This projects tests the efficacy of an occupational therapy intervention program on the driving performance of returning combat Veterans.

Role: Co-Investigator
Program Official: Ashley Fisher, M.A. | IPA, Battelle Memorial Institute Portfolio Manager
Resilience and Reintegration TATRC, USAMRMC
Address/Phone: 301-619-3146
Fax: (301) 619-7968
Email: Ashley.Fisher@tatrc.org

OVERLAP

There are no overlaps in aims or objectives between the proposed project and current projects.

Other Support

Webster, J

CURRENT

Title: Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators
PI: Alison Pruziner
Funding Agency: BADER Consortium
Role: Collaborator (2% Effort)

DoD W81XWH-16-2-0065
9/30/16-9/29/19
Dept. of Defense, U.S. Army Medical Research and Materiel Command
Principal Investigator: Resnik (OSRI)
Amount:$2,497,440
Title: Needs Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation
Role: Site Principal Investigator (10% Effort)

Title: Rehabilitation research and training center on physical disabilities
2013 - 2018
Agency: US Department of Education (CDF 84.133b-4)
Amount: $4,353,686
Determine barriers and facilitators of employment in Veterans with traumatic amputation(s)
Role: Collaborator

Title: Safety study of percutaneous osseointegrated implants for prosthetic attachment
Agency: VA Rehabilitation Research and Development Service(Rehab R&D) Service (1I01RX001208-01VA)
2013-2017
Amount: $840,000
Role: Collaborator and Co-Investigator

PREVIOUS

06/01/09 – 06/01/10
The Lower Extremity Feedback System: A Novel Device to Correct Gait Asymmetry and Improve Adherence to Weight-Bearing Restrictions.
Direct Costs: $33,900 Total Costs: $33,900
Funding Agency: University of Utah Technology Commercialization Office
Role: Principal Investigator

06/01/08 – 05/30/10 The Effects of Electrical Stimulation on Bone Ingrowth into Osseointegrated Implants.
Direct Costs: $34,995 Total Costs: $34,995
Funding Agency: University of Utah Technology Commercialization Office
Role: Co-Investigator

02/01/08 – 06/30/09 Development of a Resonance Frequency Device to Monitor Strength and Stability following Osseointegration.
Direct Costs: $6,000 Total Costs: $6,000
Funding Agency: Center for Contemporary Rehabilitation Research, Education & Practice
Role: Principal Investigator

05/01/06 – 05/01/08 A Lower Extremity Feedback System to Improve Symmetry of Gait Following Transtibial Amputation.
Principal Investigator: Randy J. Carson
Direct Costs: $5,000 Total Costs: $5,000
Funding Agency: Center for Contemporary Rehabilitation Research, Education & Practice
Role: Co-Investigator

Previous, Current and Pending Support

Investigator: M. Jason Highsmith

Current

Title: The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance care for Warriors and Veterans following Neuromusculoskeletal Injury of the Lower Limb
Time Commitment: 1.2 calendar months
Supporting Agency: Department of the Army - USAMRAA
Procuring Officer: Mirlene Ellison, 1077 Patchel Street, Fort Detrick MD 21702
Performance Period: 10/1/2016-9/30/2018
Level of Funding: $1,305,163
Project Goals: Determine if advanced (ADV) ankle foot orthoses (AFOs) will enable users to achieve greater levels of physical and self-reported function compared with conventional (CONV) AFOs for those ambulating at or above the independent community level of ambulation.
List of Specific Aims: Primary aim: determine if Veterans and Service Personnel ambulating at or above the independent level of community ambulation, who have experienced limb injury requiring use of an orthosis will experience improved ambulatory performance following accommodation with an ADV AFO compared to a CONV AFO. Secondary aims: (1) Determine if Veterans and Service Personnel ambulating at or above the independent level of community ambulation, who have experienced limb injury requiring use of an orthosis will experience improved self-reported function following accommodation with an ADV AFO compared to a CONV AFO. (2) Determine if Veterans and Service Personnel ambulating at or above the independent level of community ambulation, who have experienced limb injury requiring use of an orthosis will experience improvements in safety and pain measures following accommodation with an ADV AFO compared to a CONV AFO.
Overlap: None.

Title: Prosthetic Smart Socket Technology to Improve Patient Interaction, Usability, Comfort, Fit and Function Time Commitment: 1.2 cal months
Supporting Agency: U.S. Department of the Army
Procuring Officer: N/A
Performance Period: 8/1/2016-7/31/2019
Level of Funding: $1,465,001
Project Goals: Determine if this Smart Socket Technology Plus Patient Prompting (SST+P) will improve patient interaction, usability, comfort, fit, function and health economy outcomes compared with the standard of care (SOC) clinical practice protocols of fitting prosthetic socket interfaces for military, veteran and civilian transtibial amputees in the intermediate recovery stage of amputation rehabilitation.
List of Specific Aims: Primary aim: Determine if military, veteran and civilian transtibial amputees in the intermediate recovery stage will experience ***improved residual limb health*** following use with SST+P compared to more common SOC protocols. Secondary aims: (1) Determine if military, veteran and civilian transtibial amputees in the intermediate recovery stage will experience ***increased comfort and decreased pain*** following use with SST+P compared to more common SOC protocols. (2) Determine if military, veteran and civilian transtibial

amputees in the intermediate recovery stage will experience ***increased comfort and decreased pain*** following use with SST+P compared to more common SOC protocols.
Overlap: None

Title: The Effect of Prosthetic Socket Interface Design on Perspiration and Residual Limb Skin Condition for the Transfemoral Amputee
Time Commitment: 1.2 calendar months
Supporting Agency: U.S. Department of Defense (**CRMRP, MR140125**)
Procuring Officer: Sandra Rosario, USAMRAA, 820 Chandler St., Ft. Detrick, MD 21702
Performance Period: 09/15/2015-09/14/2017
Level of Funding: $912,628
Project Goals: The primary objective of this clinical trial is to determine if the DS and Sub-I alternative interface designs will decrease skin temperature, perspiration and pistoning; and improve balance, stability, gait, comfort and be preferred over the standard of care IRC interface.
List of Specific Aims: 1. Determine if transfemoral amputees of non-dysvascular etiology will experience an improved environment for the skin following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. 2. Determine if transfemoral amputees of non-dysvascular etiology will prefer DS or Sub-I interfaces compared to the standard of care IRC interface, following accommodation.
Overlap: None.

Title: Concurrent Validation of the Continuous Scale Physical Functional Performance Test (CS PFP-10) in Transfemoral Amputees
Time Commitment: 0.6 calendar months **(no salary)**
Supporting Agency: American Orthotic & Prosthetic Association
Procuring Officer: Thomas F. Fise, AOPA, 330 John Carlyle Street, Suite 200, Alexandria, VA 22314
Performance Period: 07/01/2015 – 12/31/2017 **(No Cost Extension)**
Level of Funding: $15,000
Project Goals: The primary goal of this grant is to test concurrent validity of specific domains of the Continuous Scale Physical Functional Performance (CS PFP 10) against outcome measures commonly used in persons with transfemoral amputation.
Specific Aims: To determine the concurrent validity of lower extremity related domains of the Continuous Scale Physical Functional Performance 10 (CS-PFP10) test in transfemoral amputees (TFAs).
Overlap: None.

Title: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation **(Awarded, but pending full subcontract to USF)**
Time Commitment: 0.6 calendar months
Supporting Agency: Providence VA Medical Center (prime: US Department of the Army)
Procuring Officer: N/A
Performance Period: 10/1/2016-09/30/2019
Level of Funding: $32,666

Project Goals: Provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.
List of Specific Aims: (1) Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs. (2) Quantify physical function using a battery of performance based tests. (3) Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs).
Overlap: None

Pending

Title: Resolving the Burden of Low Back Pain in Military Service Members and Veteran: A Multi-site Pragmatic Clinical Trial
Time Commitment: 1.2 cal months
Supporting Agency: Naval Medical Center San Diego (Prime: National Institutes of Health)
Procuring Officer: N/A
Project Goals:
Specific Aims:
Overlap: None

Previous

Title: Cost Efficacy of Transtibial Interventions
Time Commitment: 0.8 calendar months
Supporting Agency: American Orthotic & Prosthetic Association
Procuring Officer: Thomas F. Fise, AOPA, 330 John Carlyle St, Ste 200, Alexandria, VA 22314
Performance Period: 08/01/2015-12/31/2016
Level of Funding: $29,930
Project Goals: Evaluate the economic implications related to prosthetic care of the transtibial amputee according to the peer-reviewed literature.
Specific Aims: Conduct a comprehensive literature review of healthcare economics as it relates to transtibial prosthetic care.
Overlap: None.

Title: Gait Adaptation in Transfemoral Amputees Using Split-Belt Treadmill Training
Time Commitment: 0.4 calendar months **(effort reduced to 0.0 in June 2016)**
Supporting Agency: Orthotic & Prosthetic Education and Research Foundation (OPERF)
Procuring Officer: Kimber B. Nation, OPERF, PO Box 34635, Washington, DC 20043
Performance Period: 12/2/2014-12/1/2016
Level of Funding: $24,895
Project goals: Determine the effects of split-belt treadmill training (STGT) program on functional walking in people with unilateral transfemoral amputation (UTFA).

Specific Aims: (1) Quantify changes in gait symmetry during treadmill walking in people with UTFA following a 2-week STGT program; (2) Quantify changes in gait symmetry during over-ground walking in people with UTFA following a 2-week STGT program; (3) Assess changes in physical functional capacity in people with UTFA following a 2-week STGT program.
Overlap: None.

Title: MRI: Acquisition of a CAREN Virtual Reality System for Collaborative Research in Assistive and Rehabilitation Technologies
Time Commitments: None (equipment grant).
Supporting Agency: National Science Foundation
Procuring Officer: Deidre Coates, (703) 292-4804
Performance Period: September 1, 2012 – August 31, 2015
Level of Funding: $450,000
Project Goals: This grant is for the purchase of a Computer Assisted Rehabilitation Environment (CAREN) system.
List of Specific Aims: The CAREN system will allow rehabilitation researchers across the university the opportunity to propose research projects utilizing the CAREN's unique capabilities.
Overlap: None.

Title: Prosthetic Management Following Transtibial Amputation: A Systematic Review to Establish Assessment and Treatment Pathways
Time Commitments: 0.84 cal months
Supporting Agency: American Orthotic and Prosthetic Association
Procuring Officer: Thomas Fise, Jr., Executive Director, American Orthotic and Prosthetic Association, 330 John Carlyle Street, Suite 200, Alexandria, VA 22314
Performance Period: 1/16/2013-06/30/2014
Level of Funding: $50,000
Project Goals: The purpose of this project is to conduct a systematic literature review that will produce treatment algorithms and evidence statements supporting clinical decision making for patients following transtibial amputation.
List of Specific Aims: 1. Identify milestones and phase duration of the stages of post-amputation rehabilitation as reported in the literature for the transtibial amputee. 2. Identify interventional areas and specific interventions supported by the literature as well as the evidence strength for post-surgical rehabilitation transtibial amputees.
Overlap: None.

Title: Comparative Outcomes Assessment of the C-Leg and X2 Knee Prosthesis: A Pilot Study
Time Commitments: 0.96 calendar months (no cost extension)
Supporting Agency: Otto Bock Healthcare
Procuring Officer: Kimberly Walsh, 2 Carlson Parkway North, Suite 100, Minneapolis, MN 55447
Performance Period: January 5, 2010 – June 30, 2014
Level of Funding: $210,526
Project Goals: Compare the performance, subject satisfaction, and preference between C-Leg and Genium micoroprocessor knees in transfemoral amputees.

List of Specific Aims: Determine if a novel microprocessor knee enables more efficient ambulation. Determine if a novel microprocessor knee enables a higher level of function. Determine if a novel microprocessor knee enables a higher level of safety.
Overlap: None.

Title: A Clinical Trial Comparing Functional Performance of Voluntary Opening and Closing Body-Powered Prosthetic Terminal Devices
Time Commitments:0.18 cal months
Supporting Agency: TRS, Inc.
Procuring Officer: Robert Radocy, President/CEO, Therapeutic Recreation Systems, Inc., 3090 Sterling Circle, Studio A, Boulder, CO 80301-2338
Performance Period: 06/01/2013-01/29/2015
Level of Funding: $19,230
Project Goals: This study will compare the functional performance of voluntary opening and voluntary closing body powered prostheses. We hypothesize that the ability to sense cable tension and produce progressively higher pinch from periscapular force will result in advantages for the VC terminal device (TRS, Grip 3) in terms of proprioception, grip strength, overall function, and quality of life.
List of Specific Aims: 1. Determine if accommodation with a VC Grip 3 prehensor will result in improved grip force. 2. Determine if accommodation with a VC Grip 3 prehensor will result in improved movement symmetry and reduced compensatory motion during activity. 3. Determine if accommodation with a VC Grip 3 prehensor will result in improved function in activities of daily living by self-report.
Overlap: None.

Title: Occurrence of Impairments in Balance, Gait, Vestibular and Hearing Functions In USF Student OEF and OIF Veterans Compared to a Control Group of Non-Veteran Students
Time Commitment: 1.5 cal months
Supporting Agency: U.S. Department of Defense (W81XWH-11-1-0634)
Procuring Officer: Julieta Garcia, Telemedicine and Advanced Technology Research Center (TATRC) Irving Burton Associates, 205 Van Buren Street, Suite 150, Herndon, VA 20170
Performance Period: 09/20/2011-09/19/2014
Level of Funding: $264,600
Project Goals: Compare the occurrence of impairments in balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans, to USF non-veteran students.
List of Specific Aims: 1. Identify the occurrence and level of impairments in balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans compared to a control group of non-veteran students. 2. Determine the impact of self-reported mTBI on the objective outcomes of balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans.
Overlap: None.

Title: A Clinical Trial Comparing Functional Performance of Voluntary Opening and Closing Body-Powered Prosthetic Terminal Devices
Time Commitments:0.18 cal months

Supporting Agency: Florida High Tech Corridor
Procuring Officer: Paul R. Sanberg, Ph.D., D.Sc., USF Research Foundation, Inc. 3802 Spectrum Boulevard, Suite 100, Tampa, FL 33612-9220
Performance Period: 07/01/2013-06/30/2014
Level of Funding:
Project Goals: This study will compare the functional performance of voluntary opening and voluntary closing body powered prostheses. We hypothesize that the ability to sense cable tension and produce progressively higher pinch from periscapular force will result in advantages for the VC terminal device (TRS, Grip 3) in terms of proprioception, grip strength, overall function, and quality of life.
List of Specific Aims: 1. Determine if accommodation with a VC Grip 3 prehensor will result in improved grip force. 2. Determine if accommodation with a VC Grip 3 prehensor will result in improved movement symmetry and reduced compensatory motion during activity. 3. Determine if accommodation with a VC Grip 3 prehensor will result in improved function in activities of daily living by self-report.
Overlap: None.

Title: Metabolic and Biomechanical Measures of Gait Efficiency of Three Multi-Axial, Vertical Shock and Energy Storing-Return Prosthetic Feet During Simple & Complex Mobility Activities.
Time Commitments: 1.2 calendar months
Supporting Agency: Department of Defense (Award # W81XWH-112-0170)
Procuring Officer: Wendy A. Baker, US Army Medical Research Acquisition, 820 Chandler Street, Fort Detrick, MD 21702-5014
Performance Period: September 15, 2011 – September 14, 2014
Level of Funding: $714,744
Project Goals: Compare the effectiveness of three multi-function prosthetic feet for improving performance in physically demanding tasks and environments.
List of Specific Aims: (1)Determine if bioenergetic differences exist between feet at self-selected treadmill walking and running speeds; (2) Determine if biomechanic differences exist between feet at self-selected treadmill walking and running speeds; (3) Determine if differences in perceptive measures exist between feet at self-selected treadmill walking and running speeds; (4) Determine if time-to-completion & bioenergetic differences exist between feet during Obstacle Course performance; (5) Determine if differences in perceptive measures exist between feet during Obstacle Course performance.
Overlap: None.

Title: Comparative Outcomes Assessment of the C-Leg and X2 Knee Prosthesis: A Pilot Study
Time Commitments: 1.2 calendar months
Supporting Agency: Florida High Tech Corridor (industry seed grant to match Otto Bock grant)
Procuring Officer: Paul R. Sanberg, Ph.D., D.Sc., USF Research Foundation, Inc. 3802 Spectrum Boulevard, Suite 100, Tampa, FL 33612-9220
Performance Period: January 5, 2010 – June 30, 2013
Level of Funding: $105,203
Project Goals: The objective is to compare the performance, subject satisfaction, and preference between C-Leg and the new Otto Bock X2 knee in transfemoral amputees.

List of Specific Aims: Determine if a novel microprocessor knee enables more efficient ambulation. Determine if a novel microprocessor knee enables a higher level of function. Determine if a novel microprocessor knee enables a higher level of safety.
Overlap: None